

REMARKS

Reconsideration of the application is respectfully requested in view of the above amendments and the following remarks:

1) In response to the objection to claim 41, claim 41 has been listed as currently amended to reflect the amendment currently made to it.

2) Claims 34 – 36 and 45 are rejected under 35 U.S.C. §102(e) as being anticipated by Lindqvist et al. (6,051,747). Applicant respectfully traverses this rejection.

The Examiner states in the Office Action that Lindqvist et al. disclose a wound dressing comprising three layers, a first gel layer 3, a second polyurethane foam layer 2, and a third liquid-impervious layer 5 on a side of the dressing opposite the side of the dressing having the gel layer 3, and that "The gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the wound, excess wound fluid can be drawn into the foam material 2 and absorbed thereby."

The Lindqvist et al. foam layer is an **intermediate layer**, not an outermost layer of their multilayered composite structure. Lindqvist et al. do not have a foam layer which is an outermost layer of a composite structure, with said outermost layer having an outer surface forming the wound surface contacting outer surface of the second wound contacting side of the composite structure, as is recited in applicant's claim 34. Rather, the gel layer 3 of Lindqvist et al. is disclosed to as an outermost layer.

The Examiner contends that Lindqvist et al. disclose a foam layer that is not occluded by the gel layer 3. In particular, the Examiner states:

It is noted that the gel layer 3 does not close, but only covers, a part of the walls in an end portion of the pores of the foam material that face the

wound. Column 2, line 50-53. Thus, the foam does have a wound-contacting surface since the gel layer or adhesive layer does not cover the entire surface of the foam layer. Therefore, Lindqvist's structure and the instant invention as claimed are not structurally distinguishable and the prior art's wound dressing is capable of performing the recited intended use meaning Lindqvist's wound dressing is capable of being used as instantly suggested.

As recited in applicant's claim 34, applicant's top outermost layer which forms applicant's second wound contacting side of the applicant's multilayered composite structure comprises a foam layer, the foam layer having an outer surface, and the outer surface of the foam layer forming the wound surface contacting outer surface of the second wound contacting side of the composite structure.

In contrast to applicant's structure, Lindqvist et al. specifically state the following:

The gel layer also forms a spacing layer which prevents the foam material from coming into direct contact with the wound or skin of the wearer.

(See Lindqvist et al. at Column 2, lines 54-56.)

Further, Lindqvist et al. at Column 1, lines 41-43, state:

Even a thin gel layer will function as a spacer layer, because it covers the end part of the hole walls and therewith prevents contact between foam material and skin,...

Clearly, Lindqvist et al. does not have an outermost layer made of foam, as is called for in applicant's claim 34, in their multilayered composite structure in which such an outermost foam layer has an outer surface that forms the wound surface contacting outer surface of the second wound contacting side of the multilayered composite structure. While Lindqvist et al. have an absorbent foam layer 2, Lindqvist et al.'s foam layer 2 is not the outermost layer of their composite structure that comes into direct contact with the wound surface of a patient's wound,

since their foam layer 2 is sandwiched between two other layers (the gel layer 3 and the liquid-impervious layer 5) in the Lindqvist et al. wound dressing. While the Lindqvist et al. structure permits exudate to move from the wound along the gel-coated pores 4 of the foam material 2 into the foam material 2, the foam material 2 of Lindqvist et al. does not directly contact the wound surface. The only portion of Lindqvist et al.'s dressing that contacts the wound surface is Lindqvist et al.'s gel layer 3. Accordingly, Lindqvist et al.'s dressing is structurally distinguishable from Applicant's claimed invention defined in Applicant's claim 34.

Applicant's claim 35, 36, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

2) Claims 34, 36, 40, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Hofeditz (4,552,138). Applicant respectfully traverses this rejection.

Unlike Applicant's invention recited in Applicant's claim 34, Hofeditz does not disclose a dual-purpose wound dressing having **both** a membrane layer, which comprises a silicone-containing compound, as a bottom outermost layer of a multilayered composite structure, in which the membrane layer has an outer surface that forms a wound surface contacting outer surface that has wound healing characteristics, and a foam layer as a top outermost layer of a multilayered composite structure, in which the foam layer has an outer surface that forms a wound surface contacting outer surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the membrane layer.

While Hofeditz has a gel layer having an outer wound contacting surface, Hofeditz's gel does not comprise a silicon-containing compound, as called for in applicant's amended claim 34. Further, Hofeditz, in contrast to applicant's invention, has a foam layer as an intermediate or

cover layer. Hofeditz does not disclose a foam layer having a wound surface contacting outer surface having wound healing characteristics, as called for by Applicant's claim 34.

Accordingly, withdrawal of the rejection of claim 34 is respectfully requested.

Applicant's claims 36, 40, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

3) Claims 34 – 36, 38, 42 – 43, and 45 are rejected under 35 U.S.C. §102(b) as being anticipated by Freeman (5,681,579). Applicant respectfully traverses this rejection.

In contrast to applicant's invention recited in applicant's claim 34, Freeman, does not disclose a dual-purpose wound dressing having **both** a membrane layer, which comprises a silicone-containing compound, as a bottom outermost layer of a multilayered composite structure, in which the membrane layer has an outer surface that forms a wound surface contacting outer surface that has wound healing characteristics, and a foam layer as a top outermost layer of a multilayered composite structure, in which the foam layer has an outer surface that forms a wound surface contacting outer surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the membrane layer. Freeman discloses various wound dressings comprising a polymeric support layer and an occlusive backing layer overlaying the support layer. Typically, an adhesive layer is applied to the outer face of the support layer, or to the inner surface of an overhanging portion of the occlusive backing layer, for adhering the dressing to the skin of a patient. Freeman's occlusive backing layer does not have a wound surface contacting outer surface having wound healing characteristics, as called for in Applicant's claim 34.

Accordingly, withdrawal of the rejection of claim 34 is respectfully solicited.

Applicant's claims 35, 36, 38, 42-43, and 45 depend from Applicant's claim 34 and are patentable for the same reason. Further, these claims add additional claim elements which further define Applicant's invention over the cited reference.

4) Claims 37 and 39 – 42 are rejected under 35 U.S.C. §103(a) as being unpatentable over Lindqvist et al. (6,015,747) in view of Lorenz et al. (5,258,421) and as evidenced by US Patent 4,832,009. Applicant respectfully traverses this rejection.

None of the cited references teaches or suggests, either alone or in combination, Applicant's dual-purpose wound dressing having a membrane, which comprises a silicone-containing compound, as a bottom outermost layer of a multilayered composite structure, in which the membrane layer has an outer surface that forms a wound surface containing outer surface that has wound healing characteristics, and a foam layer as a top outermost layer of a multilayered composite structure, in which the foam layer has an outer surface that forms a wound surface contacting outer surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the membrane layer, as called for in the claims.

Neither Lindqvist nor Lorenz nor US Patent No. 4,832,009 discloses a wound dressing having both a first wound contacting side having a wound surface contacting outer surface having wound healing characteristics and a second wound contacting side having a wound surface contacting outer surface that has wound healing characteristics different from the wound healing characteristics of the outer surface of the first side. There is no suggestion to be gleaned from these references to produce a wound dressing that has **both** a first wound contacting side having a wound surface contacting outer surface that has wound healing characteristics and a second wound contacting side having a wound surface contacting outer surface that has wound

healing characteristics different from a wound healing characteristics of the outer surface of the first side. Lindqvist et al., Lorenz, and US Patent No. 4,832,009 show dressings having only one wound surface contacting outer surface for contacting a wound, and there is no suggestion in these references to use the dressings of the references as intended and also in an “up-side down” orientation, if desired, so as to provide a choice of wound healing characteristics from one dressing to a wound.

As pointed out above, Lindqvist et al. disclose a dressing that has only one wound surface contacting outer surface. Lorenz also has only one wound surface contacting outer surface, with only the gel layer of the dressing being applied to the patient’s wound. In Lorenz, the substrate layer merely provides reinforcement, a gas and liquid barrier, a support with gas and liquid permeability, and/or protection for the gel and the area of treatment, etc. In Lorenz, if the tacky gel layer is not applied to the entire substrate layer, the non-gel coated inner surface of the substrate layer may be provided with an additional adhesive which contacts the intact skin while the absorbent adhesive gel layer contacts the wound. Similarly, US Patent No. 4,832,009 has only one wound surface contacting outer surface. Accordingly, there is nothing in the references, either taken alone or in combination, that suggests a wound dressing having two different wound surface contacting outer surfaces having two different wound healing characteristics.

Moreover, as explained above, Lindqvist et al. have their foam layer sandwiched between the two outer layers of the Lindqvist et al. dressing, and neither Lorenz nor US Patent No. 4,832,009 remedy the claim element deficiency of Lindqvist et al.

Regarding the Examiner’s statement that “. . . the instantly claimed aesthetic design change does not impart patentable significance with regard to the mechanism in which the wound article functions” with regard to claim 41, Applicant notes that claim 41 does not merely recite an

aesthetic design change. Applicant appreciates the Examiner's statement that the addition of pigment is a structural change. The pigmented adhesive layer provides a visual indicator for differentiating one side of the dressing from the other side of the dressing in the field. Also, none of the references discloses pigment mixed into an adhesive connecting a translucent layer to an opaque layer to distinguish one side of the dressing from the other side of the dressing. This is structurally completely different from dyeing a membrane layer. Applicant's wound dressing permits the entire membrane layer to remain unaffected colorwise, but still have a color orienting indicator.

5) Claim 44 is rejected under 35 U.S.C. Section 103(a) as being unpatentable over Lindqvist et al. (6,015,747) by itself or in view of Freeman (5,681,579). Applicant respectfully traverses this rejection.


As explained above, Lindqvist et al. have their foam layer sandwiched between the two outer layers of the Lindqvist et al. dressing, and Freeman does not remedy the claim element deficiency of Lindqvist et al.

6) Claims 37, and 39-41 are rejected under 35 U.S.C. Section 103(a) as being unpatentable over Freeman (5,681,579) in view of Lorenz et al. (5,258,421) and as evidenced by US Patent No. 4,832,009. Applicant respectfully traverses this rejection.

Regarding the combination of Freeman in view of Lorenz, and as evidenced by US Patent No. 4,832,009, the suggestion to be drawn from these references, either taken alone or in combination, is the production of a "single-sided" dressing. These references show an adhesive layer being provided to the dressing so that it may only be used in one orientation, adhesive side down. The combination of the references fails to show any suggestion for producing a "two-sided" dressing since the disclosures of these references only show "single-sided" dressings.

- 7) If necessary, an appropriate extension of time to respond is respectfully requested.
- 8) The Commissioner is authorized to charge any additional fees which may be required to Patent Office Deposit Account No. 05-0208.

Respectfully submitted,



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